IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

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LONZA WALKERSVILLE, INC., *et al*.,	*	
Plaintiffs,	*	
v.	*	Civil Action No. 22-cv-0220-PX
MILTENYI BIOTEC, INC.,	*	
Defendant.	*	

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MEMORANDUM OPINION

Pending in this patent infringement action is Defendant's motion for claim construction pertinent to multiple claim terms in U.S. Patent Nos. 9,534,195 (the "'195 Patent"); 9,701,932 (the "'932 Patent"); 10,723,986 (the "'986 Patent"); and 10,844,338 (the "'338 Patent") (collectively, the "Smith Patents"). After holding a technology tutorial and *Markman* hearing, ECF Nos. 63 & 73, and having considered the relevant claim language, specifications and embodiments, this Court now construes the disputed terms.

I. Background

In 2014, Lonza Walkersville, Inc. ("Lonza"), a Maryland-based manufacturer of pharmaceutical products, began its joint venture with Octane Biotech, Inc. ("Octane") to further develop and commercialize the Cocoon® Platform, an "all-in-one" system that "facilitates the use of cell therapy" through "digital monitoring and control of temperature, gases, pH, and dissolved oxygen." ECF No. 1 ¶¶ 9, 15, 17. After years of work and collaboration with Lonza on cell therapy treatments, Octane was granted a series of patents related to "automated bioreactor technology," including the Smith Patents. *Id.* ¶¶ 20, 21, 23, 25, & 27. The Smith Patents are part of the same patent family and derive from U.S. Patent No. 8,492,140 (the "140

Patent" or "Parent Patent"). ECF No. 81 at 5.[1] *See also* ECF No. 83 at 9. The Smith Patents each have identical specifications and embodiments, but different claims. ECF No. 1 ¶¶ 22–28. *See also* ECF Nos. 42-5–8.

Generally, the Smith Patents cover cell culture and tissue engineering techniques for various types of cellular implants. Specifically, the patents describe a system "capable of automatically evaluating and manipulating the changing environment surrounding the developing implant such that cells progressively proliferate and differentiate into a desired implant," minimizing "human error" or need "of continual [cell] performance evaluation." ECF No. 42-5 at 26. The patents contribute a "fully automated" system that "modif[ies] the environment to support tissue development" using sensors and a microprocessor. *Id.* at 26–27. The Smith Patents, in short, cover a system that overall minimizes human intervention by automatically adjusting necessary parameters such as pH, temperature, gasses and nutrition during a series of tissue development stages. *Id.* at 27.

In 2013, Defendant Miltenyi Biotech, Inc. ("Miltenyi"), a direct competitor of Lonza, launched its ClinicMACS Prodigy® Instrument. ECF No. 42 at 7; ECF No. 1 ¶ 29. Lonza maintains that Miltenyi's device also employs cell engineering techniques that include a "fully automated, sensor-controlled process" "to maintain optimal conditions" for cell processing. ECF No. 1 ¶¶ 30–32. Thus, Lonza says the Prodigy infringes on the Smith Patents and accordingly, filed suit against Miltenyi for patent infringement. ECF No. 1 ¶¶ 68–99. Plaintiffs twice amended the complaint to correct Defendant's corporate name, ECF No. 22-1 at 1, and to add infringement counts related to two other patents (U.S. Patent Nos. 11,371,018 and 11,447,745),

[1] Lonza chose not to assert infringement of the '140 Patent. *See* ECF No. 83 at 34; ECF No. 37 ¶ 2.

ECF No. 37-1 at 1–2. The Parties next moved for this Court to construe certain claims included in the Smith Patents only.[2] ECF Nos. 41, 42, 56 & 57.

A. The Parties' Proposed Constructions

The Parties dispute several claim terms across the four Smith Patents. ECF No. 40-1. First, the Parties dispute whether the term "automatically" is sufficiently clear as written and when modifying terms such as "monitoring," "altering," "adjusting," and "readjust(ing).[3] ECF No. 40-1 (Patents '195, '932, '986, '338). Second, the Parties dispute whether the term "parameters" is to mean more than one parameter. *Id.* at 6. Third, the Parties dispute the meaning of "a proliferation substrate or scaffold supported within the bioreactor." *Id.* Fourth, Defendant Miltenyi argues the phrase "such that optimal conditions are maintained" is indefinite. *Id*.

Plaintiffs contend that the disputed terms are clear as written and do not require any claim construction. ECF No. 41 at 17–18. That said, Plaintiffs propose alternative constructions than those Miltenyi supports in the event the Court determines the claim terms are ambiguous as written.

The Parties' proposed constructions appear in bold and underlined text below:

Claim Terms and Phrases (Patent, Claim)	**Lonza's Proposed Construction**	**Miltenyi's Proposed Construction**
" . . . one or more sensors for monitoring and automatically adjusting parameters related to said cellular functions and/or generation of tissue constructs . . .	**Plain and ordinary meaning** **If construction needed:** . . . one or more sensors for monitoring and automatically **transmitting to a controller or microprocessor for** adjusting parameters related to said cellular functions and/or	**Plain and ordinary meaning:** . . . one or more sensors for monitoring and automatically adjusting**, without in process, external (human) input,** parameters related to said cellular functions

[2] On May 19, 2023, Parties stipulated to dismiss with prejudice the two additional patent infringement claims related to the Shi Patents. ECF No. 50.

[3] The Parties construe "active" and "actively" in the same manner as they construe "automatically," and the court treats them together. ECF No. 41 at 17.

The bioreactor is adapted to . . . and to automatically re-adjust the parameters in the bioreactor responsive to the status of cell proliferation and/or tissue formation to generate a desired cell population and/or tissue construct in the bioreactor." ('195 Patent, claim 1 and all asserted dependent claims)	generation of tissue constructs . . . the bioreactor is adapted to automatically monitor parameters relayed by the one or more sensors such that optimal conditions are maintained in the bioreactor and to automatically re-adjust, **without necessarily requiring human input,** the parameters in the bioreactor responsive to the status of cell proliferation and/or tissue formation to generate a desired cell population and/or tissue construct in the bioreactor.	. . . The bioreactor is adapted to . . . and to automatically re-adjust**, without in process, external (human) input and via a microprocessor,** the parameters related to said cellular functions and/or generation of tissue constructs in the bioreactor **in a manner that is** responsive to **changes in these parameters caused by** the status of cell proliferation and/or tissue formation to generate a desired cell population and/or tissue construct in the bioreactor. **For avoidance of doubt, automatically adjusting and re-adjusting parameters is distinct from maintaining pre-set and pre-determined parameters.**
" . . . said one or more sensors operatively generate signals to a central and/or onboard microprocessor to actively monitor and actively adjust the changing environmental conditions responsive to requirements of different stages of the cell culture and/or tissue development until completion of cell culture and/or tissue growth." ('932 Patent, claim 1 and all asserted dependent claims)	**Plain and ordinary meaning** **If construction needed:** . . . said one or more sensors operatively generate signals to a central and/or onboard microprocessor to actively monitor and actively adjust, **without necessarily requiring human input,** the changing environmental conditions responsive to requirements of different stages of the cell culture and/or tissue development until completion of cell culture and/or tissue growth.	**Plain and ordinary meaning:** . . . said one or more sensors operatively generate signals to a central and/or onboard microprocessor to actively monitor and actively adjust, **without in process, external (human) input,** the changing environmental conditions **in a manner that is** responsive to **changing** requirements ~~**of**~~ **caused by** different stages of the cell culture and/or tissue development until completion of cell culture and/or tissue growth. **For avoidance of doubt, to actively adjust the changing environmental conditions is distinct from maintaining pre-set and pre-determined environmental conditions.**

" . . . one or more sensors to detect physiological conditions and parameters within said bioreactor for active monitoring and active adjustment during the cell culture and/or tissue engineering process by a microprocessor; . . ." ('986 Patent, claim 1(a) and all asserted dependent claims)	**Plain and ordinary meaning** **If construction needed:** . . . one or more sensors to detect physiological conditions and parameters within said bioreactor for active monitoring and **for transmitting signals to a controller or microprocessor** for active adjustment **without necessarily requiring human input,** during the cell culture and/or tissue engineering	**Plain and ordinary meaning:** . . . one or more sensors to detect physiological conditions and parameters within said bioreactor for active monitoring and active adjustment**, without in process, external (human) input,** of said parameters during the cell culture and/or tissue engineering process by a microprocessor; **for avoidance of doubt, active adjustment of parameters is distinct from maintaining parameters;**
"actively monitoring and automatically adjusting during the proliferating and/or differentiating, via the microprocessor, the parameters of the cell culture and/or tissue engineering process to provide suitable culturing conditions within said bioreactor for a sufficient period of time to obtain the desired cells and/or tissue." ('986 Patent, claim 1(d))	**Plain and ordinary meaning** **If construction needed:** actively monitoring and automatically adjusting**, without necessarily requiring human input,** during the proliferating and/or differentiating, via the microprocessor, the parameters of the cell culture and/or tissue engineering process to provide suitable culturing conditions within said bioreactor for a sufficient period of time to obtain the desired cells and/or tissue.	**Plain and ordinary meaning:** actively monitoring and automatically adjusting**, without in process, external (human) input,** during the proliferating and/or differentiating, via the microprocessor, the parameters of the cell culture and/or tissue engineering process to provide suitable culturing conditions within said bioreactor for a sufficient period of time to obtain the desired cells and/or tissue.
"automatically adjusting comprises adjusting the temperature" ('986 Patent, claim 3)	**Plain and ordinary meaning** **If construction needed:** automatically adjusting comprises adjusting the temperature **without necessarily requiring human input;**	**Plain and ordinary meaning:** automatically adjusting comprises adjusting the temperature **without in process external (human) input**
"automatically adjusting comprises adjusting the pH" ('986 Patent, claim 4)	**Plain and ordinary meaning** **If construction needed:** automatically adjusting comprises adjusting the pH	**Plain and ordinary meaning:** automatically adjusting comprises adjusting the level of dissolved gases selected from oxygen and carbon

	without necessarily requiring human input;	dioxide **without in process external (human) input**
"automatically adjusting comprises adjusting the level of dissolved gases selected from oxygen and carbon dioxide" ('986 Patent, claim 5)	**Plain and ordinary meaning** **If construction needed:** automatically adjusting comprises adjusting the level of dissolved gases selected from oxygen and carbon dioxide **without necessarily requiring human input;**	**Plain and ordinary meaning:** automatically adjusting comprises adjusting the level of dissolved gases selected from oxygen and carbon dioxide **without in process external (human) input**
"automatically adjusting comprises adjusting the conditions related to metabolic turnover including lactic acid and/or glucose consumption" ('986 Patent, claim 6)	Plain and ordinary meaning If construction needed: automatically adjusting comprises adjusting the conditions related to metabolic turnover including lactic acid and/or glucose consumption **without necessarily requiring human input**.	Plain and ordinary meaning: automatically adjusting comprises adjusting the conditions related to metabolic turnover including lactic acid and/or glucose consumption **without in process external (human) input**
" . . . the one or more sensors configured to generate signals to a microprocessor to automatically monitor and automatically alter the changing environmental conditions responsive to requirements of different stages of the cell culture until completion of the cell culture." ('338 Patent, claim 1 and all asserted claims)	**Plain and ordinary meaning** **If construction needed:** . . . the one or more sensors configured to generate signals to a microprocessor to automatically monitor and automatically alter**, without necessarily requiring human input,** the changing environmental conditions responsive to requirements of different stages of the cell culture until completion of the cell culture.	**Plain and ordinary meaning:** . . . the one or more sensors configured to generate signals to a microprocessor to automatically monitor and automatically alter, **via said microprocessor and without in process, external (human) input,** the changing environmental conditions **in a manner that is** responsive to and caused by changes in the requirements of different stages of the cell culture until completion of the cell culture. **For avoidance of doubt, automatically altering the changing environmental conditions is distinct from automatically maintaining environmental conditions.**
"a proliferation substrate or scaffold supported within the bioreactor"	**Plain and ordinary meaning** **If construction needed:** a material that is suitable for cells to proliferate, and/or	**Plain and ordinary meaning:** . . . a 2D or 3D element that is distinct from a coating on the

('986 Patent, claim 1(b))	differentiate, and/or be maintained, supported within the bioreactor	walls of the bioreactor supported within the bioreactor
" . . . such that optimal conditions are maintained . . . " ('195 Patent, claim 1)	**Definite. Plain and ordinary meaning**	**Indefinite**
". . . parameters. . ." ('195 Patent, claim 1 and all asserted dependent claims; '986 Patent, claims 1 and 2)	**Plain and ordinary meaning** (no proposed construction)	**Plain and ordinary meaning:** . . . **two or more** parameters . . .

II. Standard of Review

"It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004). Accordingly, "claim construction analysis must begin and remain centered on the claim language itself, for that is the language the patentee has chosen to 'particularly point[] out and distinctly claim[] the subject matter which the patentee regards as his invention.'" *Id.* at 1116 (quoting *Interactive Gift Express, Inc. v. Compuserve, Inc.*, 256 F.3d 1323, 1331 (Fed. Cir. 2001)). When a claim term is disputed, "it is the court's duty to resolve it." *G.W. Aru, LLC v. W.R. Grace & Co.-Conn.*, 700 F. Supp. 3d 325, 341 (D. Md. 2023) (quoting *O2 Micro Intern. Ltd. v. Beyond Innovation Tech. Co., Ltd.*, 521 F.3d 1351, 1362 (Fed. Cir. 2008)).

Claim construction "is a matter of law exclusively for the court," *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 970 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370 (1996), but "there is no magic formula or catechism" for doing so, *Phillips v. AWH Corp.*, 415 F.3d 1303, 1324 (Fed. Cir. 2005). Instead, claims "are generally given their ordinary and customary meaning," *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996), which is "the

meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention," *Phillips*, 415 F.3d at 1312. Furthermore, when interpreting claims, courts must keep in mind that "[a] person of ordinary skill is also a person of ordinary creativity, not an automation." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007).

As for how to interpret an asserted claim, the Court "should look first to the intrinsic evidence of record, *i.e.,* the patent itself, including the claims, the specification and, if in evidence, the prosecution history." *Vitronics*, 90 F.3d at 1582. Where doubt persists, the Court may also consider "extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art." *Innova*, 381 F.3d at 1116; *see also Vitronics*, 90. F.3d at 1583 ("In most situations, an analysis of the intrinsic evidence alone will resolve any ambiguity in a disputed claim term. In such circumstances, it is improper to rely on extrinsic evidence.").

With this standard in mind, the Court turns to each of the requested claim constructions.

III. Analysis

A. "Automatically as modifying terms "adjust," "re-adjust," "alter," and "monitor."

The parties centrally dispute the use of the term "automatically" across all patents. ECF Nos. 40-1, 41 at 10, & 83 at 58. Lonza argues the term "automatically" is clear as written. ECF No. 41 at 10 & 17. More to the point, Lonza argues the term does not contemplate *no* human intervention because the specification expressly discusses certain processes that require some human activity such as cell sampling, loading of reagents, and removing samples or waste fluid. ECF No. 41 at 15. Thus, the term "automatically" cannot be read to exclude all human inputs. *Id. See also* 42-5 at 32 (patent describing the processes as "require[ing] *minimal* human intervention."). "'[M]inimal' is not 'none.'" ECF No. 41 at 15.

Miltenyi, for its part, correctly highlights that the essential purpose of the Smith Patents was to automate the cell culturing process itself, thus removing "labor intensive" human intervention susceptible to "human error" during the cell culturing process. ECF No. 42 at 20; ECF No. 42-5 at 26. The Smith Patents' specification describes a system that "eliminates operator intervention," thereby "reduc[ing] the possibility of inadvertent contamination." ECF No. 42-5 at 31. Indeed, even Plaintiffs concede that "the claim language itself and the patent specification are directed to automation of cell culture." ECF No. 41 at 18.

Further, an intrinsic reading of the Smith Patents' specification makes clear that the monitoring, adjustment, alteration, or readjustment of parameters or environmental conditions is in fact fully automated. *See* ECF No. 42-5 at 26 (Smith Patent solves the problem of prior systems because it automatically evaluates and manipulates the changing environment surrounding the developing implant). *See also id.* at 32 (noting that temperature sensors, gas sensors, and the environmental control unit are controlled by a central processing unit ("CPU")). In that vein, "[d]eviations from ideal conditions are sensed by a variety of sensors present within the bioreactor and the signals generated are monitored by the central processor. As such, changes in environmental conditions such as but not limited to pH, temperature and dissolved gases can be automatically monitored and altered as required." *Id*. at 27. The Patents, therefore, explicitly describe an automated adjustment of environmental conditions.

Likewise, the word "automated" predominates in the Smith Patents' description of the cell culturing process, to include digestion, proliferation, seeding, differentiation, and the mixing and delivery of reagents. ECF No. 42-5 at 28. Indeed, the prosecution history reinforces that the invention's automation of such processes remained central to the issuance of the Patents themselves. *See* ECF Nos. 42-10 at 28–29 & 42-11 at 26–27 & 36. *See also Graham v. John*

Deere Co., 383 U.S. 1, 33 (1966) ("[A]n invention is construed not only in light of the claims, but also with reference to the file wrapper or prosecution history in the Patent Office."). Thus, the Court agrees with Miltenyi that with respect to the disputed claims in the Smith Patents, "automatically" describes the cell culturing process and, as to that process, must mean without human intervention.

That said, the Court cannot agree with Miltenyi's position that the Patent language must be modified as it suggests. Wherever the term "automatically" appears in the Smith Patents, Miltenyi urges the Court effectively add the language, "without in process, external (human) input and via a microprocessor," as well as the caveat, "for avoidance of doubt, automatically adjusting and re-adjusting parameters is distinct from maintaining pre-set and pre-determined parameters." ECF No. 40-1 at 2–5. The Court finds this language redundant, confusing, and unnecessary.

Miltenyi's "in process" language is unnecessary because each claim describes with specificity the aspect of the process that is automated; thus, the Patent as drafted makes clear that "automatically" applies to the described processes. The term "external" is unnecessary because human input during the cell culturing process is, by definition, "external" to the embodiment of the patent. And the Court need not add the "avoidance of doubt" clause, given that the difference between the terms "alter" and "maintain" is evident. *See Vir2us, Inc. v. Invincea, Inc.*, 2016 WL 453486, at *6 (E.D. Va. Feb. 5, 2016) (rejecting construction where additional modifying word was redundant); *Shibumi Shade, Inc. v. Beach Shade LLC*, 2022 WL 390839, at *6 (E.D.N.C. Feb. 8, 2022) (rejecting claim construction that was redundant and confusing); *Morpho Detection, Inc. v. Smiths Detection Inc.*, 2012 WL 5194076, at *13 (E.D. Va. Oct. 19,

2012) (noting that construction is unnecessary for commonly understood words with widely accepted meanings).

Furthermore, the Smith Patents make clear that the invention automatically adjusts applicable parameters in response to cell proliferation and tissue formation, not other parameters. No additional language is necessary to further clarify this fundamental claim. ECF No. 40-1 at 2. *See also Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998) ("The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction.").

While the Court agrees to some extent with Plaintiffs' proposed language suggesting that wherever the term "automatically" is used, the pertinent phrase may include "without necessarily requiring human input, "necessarily requiring" is confusing and redundant. Accordingly, the Court finds that for clarity, the claim term "automatically" should be modified to include the phrase, "without human input." *See Dialect, LLC v. Amazon.com Inc.*, 2024 WL 1859806, at *2 (E.D. Va. Apr. 29, 2024) (quoting *Homeland Housewares, LLC v. Whirlpool Corp.*, 865 F.3d 1372 (Fed. Cir. 2017). ("A court may adopt a definition not proposed by either party if that construction best fits the evidence before it."). Thus, the Court adopts the following claim constructions:

Claim Terms and Phrases (Patent, Claim)	**Court Claim Construction**
" . . . one or more sensors for monitoring and automatically adjusting parameters related to said cellular functions and/or generation of tissue constructs . . . The bioreactor is adapted to . . . and to automatically re-adjust the parameters in the	. . . one or more sensors for monitoring and automatically adjusting, **without human input,** parameters related to said cellular functions and/or generation of tissue constructs . . . the bioreactor is adapted to automatically monitor parameters relayed by the one or more sensors such that optimal conditions are maintained in the bioreactor and to automatically re-adjust, **without human input**, the parameters in the bioreactor responsive to the status of cell proliferation and/or tissue

bioreactor responsive to the status of cell proliferation and/or tissue formation to generate a desired cell population and/or tissue construct in the bioreactor." ('195 Patent, claim 1 and all asserted dependent claims)	formation to generate a desired cell population and/or tissue construct in the bioreactor.
" . . . said one or more sensors operatively generate signals to a central and/or onboard microprocessor to actively monitor and actively adjust the changing environmental conditions responsive to requirements of different stages of the cell culture and/or tissue development until completion of cell culture and/or tissue growth." ('932 Patent, claim 1 and all asserted dependent claims)	. . . said one or more sensors operatively generate signals to a central and/or onboard microprocessor to actively monitor and actively adjust, **without human input**, the changing environmental conditions responsive to requirements of different stages of the cell culture and/or tissue development until completion of cell culture and/or tissue growth**.**
" . . . one or more sensors to detect physiological conditions and parameters within said bioreactor for active monitoring and active adjustment during the cell culture and/or tissue engineering process by a microprocessor; . . ." ('986 Patent, claim 1(a) and all asserted dependent claims)	. . . one or more sensors to detect physiological conditions and parameters within said bioreactor for active monitoring and for active adjustment **without human input**, during the cell culture and/or tissue engineering
"actively monitoring and automatically adjusting during the proliferating and/or differentiating, via the microprocessor, the parameters of the cell culture and/or tissue engineering process to provide suitable culturing conditions within said bioreactor for a sufficient period of time to obtain the desired cells and/or tissue."	actively monitoring and automatically adjusting, **without human input**, during the proliferating and/or differentiating, via the microprocessor, the parameters of the cell culture and/or tissue engineering process to provide suitable culturing conditions within said bioreactor for a sufficient period of time to obtain the desired cells and/or tissue**.**

('986 Patent, claim 1(d))	
"automatically adjusting comprises adjusting the temperature" ('986 Patent, claim 3)	automatically adjusting comprises adjusting the temperature **without human input**;
"automatically adjusting comprises adjusting the pH" ('986 Patent, claim 4)	automatically adjusting comprises adjusting the pH **without human input**;
"automatically adjusting comprises adjusting the level of dissolved gases selected from oxygen and carbon dioxide" ('986 Patent, claim 5)	automatically adjusting comprises adjusting the level of dissolved gases selected from oxygen and carbon dioxide **without human input**;
"automatically adjusting comprises adjusting the conditions related to metabolic turnover including lactic acid and/or glucose consumption" ('986 Patent, claim 6)	automatically adjusting comprises adjusting the conditions related to metabolic turnover including lactic acid and/or glucose consumption **without human input**.
" . . . the one or more sensors configured to generate signals to a microprocessor to automatically monitor and automatically alter the changing environmental conditions responsive to requirements of different stages of the cell culture until completion of the cell culture." ('338 Patent, claim 1 and all asserted claims)	. . . the one or more sensors configured to generate signals to a microprocessor to automatically monitor and automatically alter, **without human input**, the changing environmental conditions responsive to requirements of different stages of the cell culture until completion of the cell culture.

The Court next turns to the second disputed term.

B. Parameters

The parties ask the Court to resolve whether the term "parameters" is sufficiently clear to convey that it must be read always as describing at least two parameters. ECF No. 41 at 30; ECF No. 57 at 17. *See also Apple Inc. v. MPH Techs. Oy*, 28 F.4th 254, 261 (Fed. Cir. 2022) ("In accordance with common English usage, we presume a plural term refers to two or more items.").

Miltenyi proposes constructing "parameters" to mean "two or more parameters," ECF No. 40-1 at 6, and argues that its proposed construction clarifies the fact that "parameters" is a plural term. ECF No. 42 at 21. Lonza counters that "[i]f Defendant's construction is to clarify that the term 'parameters' is plural, the construction is unnecessary because the term is already plural." ECF No. 41 at 30. Thus, Lonza says that the claim language is clear as written and does not propose a construction. ECF No. 40-1 at 6.

To the extent that any disagreement between the Parties persists, it stems from Lonza's assertion that "when there is one sensor, it can adjust one parameter." ECF No. 41 at 30. The Court agrees with Miltenyi that the prosecution history makes clear the invention contemplated the use of more than one parameter in the bioreactor. ECF No. 57 at 18. And that "[t]he prosecution history may be given substantial weight in construing a term when the term is added by amendment." *Bd. of Regents of the Univ. of Tex. Sys. v. BENQ Am. Corp.,* 533 F.3d 1362, 1369 (Fed. Cir. 2008). But where Miltenyi strays from the prosecution history is to suggest that every sensor in the bioreactor adjust at least two parameters. *See* ECF No. 42 at 22. The prosecution history does not support that limitation.

During the *Markman* hearing, Lonza's counsel clarified that one sensor may control multiple parameters in the bioreactor, or otherwise, one sensor may control one parameter given there are multiple sensors in the bioreactor. *See* ECF No. 83 at 96–97. Miltenyi agreed. *Id.* at

100. Accordingly, the Court concludes that the claim language is clear as written and should be construed such that when the bioreactor has multiple sensors, each could monitor only one parameter.

C. "A proliferation substrate or scaffold supported within the bioreactor"

The parties next dispute whether the phrase "a proliferation substrate or scaffold supported within the bioreactor" is clear as written. *See* ECF No. 40-1 at 6. Miltenyi proposes that the Court wholly replace this language with the phrase "a 2D or 3D element that is distinct from a coating on the walls of the bioreactor supported within the bioreactor." ECF No. 40-1 at 6; ECF No. 42 at 23. Miltenyi seeks this alternative construction to clarify that the invention does not include application of a coating within the bioreactor. ECF No. 57 at 20.

The Plaintiffs disagree and for good reason. The Smith Patents' specification includes embodiments in which "the proliferation substrate" *is* a coating on the walls of the bioreactor. ECF No. 41 at 25–26. Indeed, the specification expressly establishes the option to either use the actual surfaces of the bioreactor for proliferation by coating them with biomaterials that enhance proliferation *or* to insert a separate proliferation substrate or scaffold. ECF No. 42-5 at 36. Specifically, "[i]n one embedment Skelite may be used to enhance cell proliferation through its use as a coating on the walls of the bioreactor, as a thin film on the proliferation substrate." ECF No. 42-6 at 27.

Because claims "must be read in view of the specification, of which they are a part," and the specification is usually dispositive in determining the meaning of a disputed term, the Court finds that Miltenyi's claim construction is improper, and a proliferation substrate or scaffold supported within the bioreactor may include a substrate on the wall of the bioreactor. *See Dynatemp Int'l, Inc. v. R421A LLC*, 560 F. Supp. 3d 969, 975 (E.D.N.C 2021) (quoting *Phillips*,

415 F.3d at 1315). Furthermore, this Court credits that a proliferation substrate is "a material that provide[s] the functions a cell can attach to [] so that they either maintain [] viability and [] can further grow up," and finds Lonza's claim construction appropriate. *See* ECF No. 83 at 194. The Court will make no changes to it.

D. Definiteness of "Optimal Conditions"

Last, as to whether the term "optimal conditions" requires further definition. The Patent Act's definiteness provision requires that a patent "conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor . . . regards as the invention." 35 U.S.C. § 112(b). "Whether a claim complies with the definiteness requirement . . . is a matter of claim construction." *Noah Systems, Inc. v. Intuit Inc.*, 675 F.3d 1302, 1311 (Fed. Cir. 2012). Although patent terms must be specific enough to afford clear notice of what is claimed, "absolute precision is unattainable" and "some modicum of uncertainty ... is the price of ensuring the appropriate incentives for innovation." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901, 910 (2014). But if a patent's "claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention," then the claims are invalid for indefiniteness. *Id.* at 901. The party who asserts indefiniteness bears the burden of proving it by clear and convincing evidence. *Dow Chem. Co. v. Nova Chems. Corp. (Canada)*, 809 F.3d 1223, 1227 (Fed. Cir. 2015).

Miltenyi argues that the claim "such that optimal conditions are maintained" is indefinite because the term "optimal" is too ambiguous. ECF No. 57 at 23; *see also* ECF No. 42 at 26. Accordingly, says Miltenyi, the Smith Patents must particularize the optimal conditions for every listed cell and tissue type compatible with its bioreactor, or else the term is indefinite. ECF 42 at

28. Lonza, in response, reasserts that the term is sufficiently definite because "a [person of skill in the art ("POSA")] would know what optimal conditions are," and how to choose the optimal conditions depending on desired cell types and outcomes. ECF No. 41 at 28.

It is well established that where a POSA could perform testing to find the "optimal condition," the term is sufficiently definite. *See Trustees of Purdue Univ. v. Wolfspeed, Inc.*, 2023 WL 5020573, at *11 (M.D.N.C. Aug. 7, 2023). This is true even where there may be some small variations in the "optimal condition." *See id*. at 10. In this instance, Lonza and Miltenyi agree that a POSA would be someone with a degree in the field of biomanufacturing, biochemical engineering, or biomedical engineering with multiple years of post-graduate experience. ECF No. 41 at 10; ECF No. 42-4 ¶ 32. And Miltenyi concedes that a skilled artisan would undoubtedly understand how the functions of the bioreactor and various growth factors would affect a cell population or tissue construct. ECF No. 42 at 27–28. Therefore, a POSA could engage the bioreactor to find the optimal conditions for any compatible cell or tissue. ECF No. 56 at n. 9.

Miltenyi provides no evidence to the contrary. Instead, Miltenyi states that "the intrinsic record fails to provide a skilled artisan with objective boundaries as to which criteria, among an unlimited number of criteria, determines whether a condition is optimal." ECF No. 42 at 28. But the Smith Patents' specification enumerates the limiting factors that can contribute to an optimal condition: "temperature, pH, dissolved gases selected from oxygen and carbon dioxide, metabolic turnover inclusive of lactic acid and glucose consumption, optical density, light scattering, and images of cell/tissue proliferation." ECF No. 41 at 27; ECF 42-5 at 42. Moreover, the same criteria are directly linked to the limits of cell viability and growth ex vivo. *See* ECF No. 42-16 at 9–10, 12–13. The boundaries of the optimal conditions, therefore, are

objective and defined. Because Miltenyi failed to prove by clear and convincing evidence that the claim would fail to inform a POSA of the scope of the invention, the Court finds "optimal conditions" to be sufficiently definite. The term remains as written.

IV. Conclusion

For the foregoing reasons, and in response to Miltenyi's First challenge, the Court hereby modifies the Smith Patent language by inserting the phrase "without human input" to clarify the term "automatically" as used to describe the invention. As to Miltenyi's Second challenge, the Court finds, and the Parties now agree, that "parameters" is clear as written. The Court rejects Mitenyi's Third and Fourth challenge, and the patent language as written will remain unchanged.

So Ordered.

Date: December 3, 2024

/S/
PAULA XINIS
UNITED STATES DISTRICT JUDGE